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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,321	08/04/2003	Unchalee Kositprapa	AXP-0003B	7853

7590 04/13/2006

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EXAMINER

ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/634,321	Applicant(s) KOSITPRAPA, UNCHALEE	
	Examiner James H. Alstrum-Acevedo	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-22 are pending.

Election/Restrictions

The Examiner acknowledges receipt of Applicant's election with traverse of an antidepressant as the elected invention and the species elections of paroxetine as the active ingredient and methacrylate polymers as the single enteric coating component in the reply filed on September 22, 2005. The Applicant's arguments regarding the traversal of the restriction requirement were found persuasive. The previous restriction requirement, described in the communication from the office mailed on August 5, 2005, is withdrawn. A search of the prior art found the generic species to be coextensive. The species election is withdrawn. All claims are under consideration in the instant office action.

Priority

The later-filed application must be an application for a patent for an invention, which is also disclosed, in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application Nos. 09/335,575 (U.S. Patent No. 6,077,541), 08/974,489 (U.S. Patent No. 6,096,340), and 09/143,167 (U.S. Patent No.

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6,172,548), fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The cited applications do not provide support for water-insoluble binders. Although binders are broadly taught in the disclosures of the previously filed applications, now U.S. patents, these do not teach water-insoluble binders and mention water-soluble binders, which are the preferred binders. Therefore, priority is only granted to application 09/597,206 (now U.S. Patent No. 6,602,522) with a filing date of June 20, 2000.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The use of the trademarks AVICEL[®] (pg. 13 Table; pg. 14 Table; pg. 15, lines 6 and 11; pg. 16 Table; pg. 18 Table and line 14; pg. 21 Table and line 16; pg. 22 Table; pg. 23 Table and line 7; and pg. 24 Table and line 9), PLASDONE[®] (pg 14 Table; pg 19 Table; pg 21 Table; Tables on pages 22-23), and EUDRAGIT[®] (Tables on pages 13-15, 18, 20, and 23; pg. 11, line 1; pg. 14, line 15; pg. 15, line 14; and pg. 17, line 15) have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amount range recited for the processing aid in claim 9 (i.e. from 10-80 wt.%) is not described in the specification. It is noted that the only ranges for amounts of processing aids disclosed in the specification are found on page 11, lines 6-8, and include an amount from about 10 to about 50 wt. % and preferably an amount from about 20 to about 40 wt. %.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 7, and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Morella et al. (WO 94/05262).

Morella discloses a sustained release matrix composition wherein the sustained release particles comprise a core element comprising a low solubility active ingredient and at least two polymers. The core is optionally coated with an enteric coating (title and abstract).

Morella discloses that the term “microparticle composition” means pellets or granules (pg. 2, lines 36-38). The term “granules” encompasses the term powder. The active ingredient

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may be selected from the group of dihydropyridines, including nifedipine, diltiazem, flunarizine, and pharmaceutically acceptable isomers, salts, and mixtures thereof (pg. 3, lines 17-26). Nifedipine is also **a potent inhibitor of coronary artery spasm** (i.e. it is inherently an anti-arrhythmic drug) (pg. 4, lines 7-8). The polymers used in the core may include at least one water-soluble polymer, including **polyvinylpyrrolidone, hydroxypropyl cellulose**, hydroxypropyl methylcellulose, polyethylene glycol, **polyvinyl alcohol**, and mixtures thereof. The core may also include a substantially insoluble polymer (enteric polymer), including **cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, cellulose phthalate, methacrylic acid copolymer**, hydroxypropyl methylcellulose acetate succinate, shellac, etc. Although the italicized, underlined, bold-faced water-soluble/insoluble polymers listed above and disclosed by Morella are not called binders; they are inherently binders, as evidenced by Applicant's disclosure on page 10 of the instant specification identifying them as such. The bold-faced polymers listed above and taught by Morella are polymers for use as enteric coatings, as recited in claim 7. When the composition is coated, the coating may be formed by an enteric polymer as disclosed above (see pg. 4). A general disclosure of the amounts of ingredients can be found on page 8, lines 2-18). These disclosures may be found on page 4, lines 15-39 and page 5, lines 1-6).

Morella discloses that the core element may also comprise from 0 to approximately 50% w/w of a filler, selected from the group including, **silicon dioxide**, titanium dioxide, **talc**, starch, microcrystalline cellulose, etc. (page 5, lines 37-39; pg. 6 lines 1-2). Regarding the method of claims 21-22, the procedural limitations of this method are inherently met by the disclosure of

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Morella, because it merely requires "providing at least one water insoluble binder and at least one water soluble binder in the core.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (WO 94/05262).

Morella does not anticipate claims 8-9, because Morella does not teach the inclusion of processing aids with the enteric polymer, when used to coat a core comprising an active agent, a water-soluble polymer, and a water-insoluble polymer.

The teachings of Morella have been set forth above.

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention that the filler materials may be combined with the enteric coating polymer,

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because Morella teaches a core that comprises an active, a water-soluble polymer, and a water-insoluble enteric polymer. The filler materials disclosed by Morella as filler, specifically talc and silicon dioxide, are also processing aids, as identified by the Applicant on page 11 of the instant specification. It would have been apparent to a skilled artisan that excipients used as fillers may have different functions within a given composition, such as processing aids.

Claims 11-14 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (94/05262) in view of Kanios et al. (U.S. Patent No. 5,719,197) ("Kanios").

The teachings of Morella have been set forth above.

Morella lacks the teaching of compositions wherein the active agent is an analgesic, anti-convulsant, antidiabetic, anti-histamine, or anti-psychotic.

Kanios teaches compositions for topical application comprising a therapeutically effective amount of a pharmaceutical agent, bioadhesive carrier, solvent, and a clay as well as methods of administration of said compositions to mammals (abstract).

Acceptable pharmaceutical agents taught by Kanios include **analgesics** (e.g. **fenoprofen, indoprofen, ketoprofen, naproxen, and salicylic acid**) (col. 13, lines 59-67; col. 14, lines 1-30), **anti-convulsants** (e.g. **clonazepam, carbamazepine, and valproic acid**) (col. 18, lines 31-46), **antidiabetics** (e.g. **biguanides and sulfonylurea derivatives**) (col. 19, lines 14-24), **antihistamines (e.g. loratadine)** (col. 19, line 67 through col. 20, line 31), and **antipsychotics** (e.g. **phenothiazines, chlorpromazine thioridazine, trifluoperazine, and triflupromazine**)

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(col. 24 6-31). Kanios discloses a wide variety of other pharmaceutical active agents (col. 12, lines 57-67 through col. 31, line 56).

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Morella and Kanios, because Morella teaches controlled release formulations in which the core comprises an active agent and Kanios teaches a plethora of pharmaceutical active agents. Furthermore, it would have been obvious, because, as the Applicant stated in the response to the restriction requirement mailed on September 22, 2005, "Applicant disagrees with the characterization that the species disclosed are patentably distinct." In other words, there is no patentable distinction between the active agents included in a controlled release formulation, and a skilled artisan would have been motivated to rely upon the teachings of Kanios as a convenient concise listing of a wide variety of pharmaceutical active agents, which in the course of routine experimentation and optimization, would be substituted for the actives taught by Morella to obtain controlled release formulations of these other active agents. For the reasons discussed above, a person of ordinary skill in the art would have had a reasonable expectation of success upon combination of the teachings of Morella and Kanios.

Claims 4 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (WO 94/05262) in view of Curatolo et al. (U.S. Patent No. 6,068,859) ("Curatolo").

The teachings of Morella have been set forth above.

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Morella lacks the teaching of an optional alkaline material, additional processing aids included with the enteric coating material in amounts from 10-80 wt. %, and sodium lauryl sulfate as a surfactant.

Curatolo teaches controlled-release dosage form of azithromycin having an improved side effect profile (abstract). Azithromycin is an active agent. Specific embodiments can be in the form of a sustained release oral dosage form, a delayed release oral dosage form, or, alternatively, an oral dosage form, which exhibits a combination of, sustained release and delayed release characteristics (col. 2, lines 3-9).

Curatolo teaches that an aspect of his invention provides a process for preparing sustained-release dosage forms of azithromycin, comprising granulating azithromycin bulk drug substance with a binder, coating the granulation with a polymer coating of controlled permeability to azithromycin, and coating said granulation with additional polymer of controlled permeability to azithromycin until to effect the desired sustained release rate or profile (col. 4, lines 9-13). A variety of dosage forms including multiparticulate beads, etc. may be multiply loaded into a gelatin capsule, or may be compressed into a tablet (col. 4, lines 29-34). In one embodiment, the matrix may contain azithromycin and an amount of a hydrophilic polymer sufficient to provide a useful degree of control over the azithromycin dissolution. Hydrophilic polymers useful for forming the matrix include hydroxypropylmethyl cellulose (HPMC), poly(vinyl alcohol), etc. The dissolution rate may also be controlled by the use of water-soluble additives such as NaHCO₃ (a sodium salt of carbonic acid) and water-soluble polymers, including PVP (polyvinylpyrrolidone) (col. 8, lines 30-38, 48-53).

Curatolo teaches that in one embodiment, the composition comprises a sustained release matrix in which azithromycin is dispersed in a hydrogel, including poly(methacrylic acid), polyvinylalcohol, and their copolymers (col. 10, lines 12-13, 33-38). Polymethacrylic acid has been identified by the Applicant as an example of a water-insoluble binder (claim 21, pg. 10 of the specification) and polyvinyl alcohol was identified as a water-soluble binder (pg. 10 of the specification).

Curatolo teaches an exemplary azithromycin core formulation in Example 31, Table 31-1, which includes sodium lauryl sulfate, calcium phosphate dibasic (a calcium salt of phosphoric acid), etc. Exemplary tablet coating formulations are taught in Example 33, Table 33-1, and include a mixture of EUDRAGIT[®] L and EUDRAGIT[®] S mixed with talc and other ingredients. EUDRAGIT-L[®] and EUDRAGIT-S[®] are anionic copolymers of methacrylic acid and methylmethacrylate (col. 17, lines 60-61).

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Morella and Curatolo, because both inventors teach controlled release formulations, in which the core comprises an active agent in admixture with additional polymeric ingredients, and a coating of said core. A skilled artisan would have been further motivated to combine the teachings of Morella and Curatolo, because Curatolo teaches additional components, which may be added to core formulations to adjust the active dissolution rate, including sodium bicarbonate (NaHCO₃) and similar polymeric binding agents, including polyvinyl alcohol and hydroxypropyl cellulose. A person of ordinary skill in the art would have had a reasonable expectation of success upon combination of the prior art teachings, because both inventors teach controlled release formulations comprising a core comprising an active in

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admixture with polymeric ingredients, wherein said core may be coated. Regarding the amount of excipients utilized in the coating formulation, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Claims 4-5, 11-13, 15, 16, and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (WO 94/05262) in view of Acharya (U.S. Patent No. 5,686,094) ("Acharya").

The teachings of Morella have been set forth above.

Morella lacks the teaching of an optional alkaline material and an active agent that is an antilipemic, analgesic, anti-convulsant, diuretic, or an anti-psychotic.

Acharya teaches a polymeric delivery system formed by a polycarbophil type composition with an active agent. The resulting product is useful as a carrier or coating of active compositions, or for the controlled or sustained release of active agents that are drugs, etc. (abstract).

Acharya teaches that the compositions are especially useful for local, parenteral, buccal, gingival, and oral controlled release of active compositions, such as pharmaceuticals, and take

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the form of granules, encapsulated capsules, tablets, chewable gums, ingestible and implantable boluses, candies, lollipops, pourable liquids, gels, suppositories and the like (col. 1, lines 8-13).

Acharya teaches that the delivery systems of the present invention are formed by the use of a calcium polycarbophil type composition with an active agent, optionally in the presence of water (col. 4, lines 58-61). The polycarbophil component may be present in the form of its calcium salt, wherein the calcium cation is introduced by the inclusion of a calcium-containing compound, including calcium hydroxide (col. 12, lines 3-11).

Acharya teaches that the active agent may include chlorothiazide (a thiazide diuretic), clofibrate (an antilipemic that is a fibric acid derivative), phenytoin (anticonvulsant), phenobarbital (sedative and antipsychotic), chlorpromazine (muscle relaxant and antipsychotic), antidepressants, antihistamines, and analgesics (e.g. ibuprofen). The actives may be used singly or as a mixture of two or more agents (col. 7, lines 63, 67; col. 8, lines 11-12, 46-48, 66; and col. 9, lines 1 and 7-8). Other additives may also be incorporated with the actives, including calcium carbonate (a calcium salt of carbonic acid), calcium hydrogen phosphate (calcium salt of phosphoric acid), talc, and binders (col. 9, lines 30-31, 43-46).

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Morella and Acharya, because both inventors teach controlled release formulations comprising a core comprising an active agent. Further motivation for a skilled artisan to combine the teachings of Morella and Acharya is that both references are in the field of controlled release pharmaceutical formulations. A skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings,

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because both references teach controlled release formulations comprising an active core and a coating and the oral administration of said formulations.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4, 7, and 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 7-9 of U.S. Patent No. 6,174,548 (USPN '548) in view of Morella (WO 94/05262). Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims are substantially overlapping in scope and are mutually obvious. Both claim sets recite compositions for oral administration wherein the core comprises an active ingredient and a binder, wherein an enteric coating agent coats the core. The dependent claims of the instant application and USPN

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'548 also recite similar alkaline agents (e.g. lysine and arginine) and the Markush group of enteric coating materials recited in claim 7 of the instant application and claim 3 of USPN '548 are identical. Both sets of cited claims also recite a method for manipulating the bioavailability of a pharmaceutical dosage comprising the same steps, wherein the water insoluble binder is a polymethacrylic acid copolymer. The claims of USPN '548 do not recite a water insoluble binder. This deficiency is cured by the disclosures of Morella, as set forth above, regarding the incorporation of an insoluble polymer binder in the core of a controlled release formulation. Although the claims of USPN '548 do not recite a controlled release property of the dosage formulations, it would have been apparent to a skilled artisan cognizant of the teachings of Morella and USPN '548, that the resulting compositions would have said property. Therefore, claims 1-2, 4, 7, and 10 of the instant application are prima facie obvious over claims 1-2, 4, 7-9 of USPN '548.

Claims 1, 4-10, 21, and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 5-11, 16, and 18-19 of U.S. Patent No. 6,602,522 (USPN '522). Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims are substantially overlapping in scope and are mutually obvious. Both claim sets recite compositions wherein the core comprises an active ingredient, at least one water-soluble binder, and at least one water insoluble binder, wherein a single layer of an enteric coating agent coats the core. The dependent claims of the instant application and USPN '522 also recite the same Markush group of optional alkaline agents (claims 4-5 in the instant application and USPN '522). Both sets of cited claims also recite a method for manipulating the bioavailability of a pharmaceutical dosage comprising the

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same steps, wherein the water insoluble binder is a polymethacrylic acid copolymer. Therefore, claims 1, 4, 5-10, 21, and 22 of the instant application are prima facie obvious over claims 1-2, 4, 5-11, 16, and 18-19 of USPN '522.

Claims 1-3, 5-11, and 13-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 7-9 of U.S. Patent No. 6,733,778 (USPN '778) in view of Morella (WO 94/05262). Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims are substantially overlapping in scope and are mutually obvious. Both claim sets recite compositions wherein the core comprises an active ingredient and a binder, wherein an enteric coating agent coats the core. The dependent claims of the instant application and USPN '778 also recite similar alkaline agents (e.g. lysine and arginine) and the Markush group of enteric coating materials recited in claim 7 of the instant application and claim 5 of USPN '778 are identical. Both sets of cited claims also recite a method for manipulating the bioavailability of a pharmaceutical dosage comprising the same steps, wherein the water insoluble binder is a polymethacrylic acid copolymer. The claims of USPN '778 do not recite a water insoluble binder. This deficiency is cured by the disclosures of Morella, as set forth above. Therefore, claims 1-3, 5-11, and 13-16 of the instant application are prima facie obvious over claims 1-2, 4, 7-9 of USPN '778.

Other Matter

The Examiner noted that there is almost an entire page break between the text on the top of page 3 of the specification and the text on page 4. The Examiner respectfully suggests

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removal of the page break. The Examiner respectfully suggests inserting a space between the number 80 and "wt%."

Conclusion

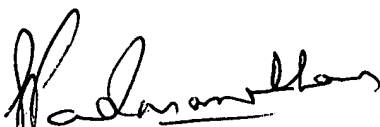
Claims 1-22 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.
Examiner


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER